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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/913,498	08/16/2001	Emmanuel Lazaridis	114205.204	2508
21901	7590	02/24/2004		
SMITH & HOPEN PA 15950 BAY VISTA DRIVE SUITE 220 CLEARWATER, FL 33760			EXAMINER MARSCHER, ARDIN H	
			ART UNIT 1631	PAPER NUMBER

DATE MAILED: 02/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

S.A.M.

**Office Action Summary****Application No.**

09/913,498

**Applicant(s)**

LAZARIDIS, EMMANUEL

**Examiner**

Ardin Marschel

**Art Unit**

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**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --****Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 02 December 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) 7-10 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6 and 11-23 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-23 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |  |
|--|--|
| <p>1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)</p> <p>2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)</p> <p>3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)</p> | <p>4) <input type="checkbox"/> Interview Summary (PTO-413)<br/>Paper No(s)/Mail Date. _____</p> <p>5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)</p> <p>6) <input type="checkbox"/> Other: _____</p> |
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### **DETAILED ACTION**

Applicant's election without traverse of Specie A (A-1: Genetic analysis directed to a cancer or tumor medical condition) (claims 1-6 and 11-23) in the Paper, filed 12/2/03, is acknowledged.

### **NON-STATUTORY SUBJECT MATTER**

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-6 and 11-23 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Consideration of the "Computer-Related Inventions" section of the MPEP at section 2106, Part IV, subpart B, has revealed that the above listed instant claims are directed to non-statutory subject matter without requiring performance of a result outside of a computer or data manipulation method. Thus, the manipulation of data or conversion of data, in this case, classifying objects, is the claimed subject matter without any physical transformation outside of a computer or data manipulation.

### **VAGUENESS AND INDEFINITENESS**

Claims 1-6, 12, 15, 16, and 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 2, line 1, the phrase "the formula of claim 1" is cited which may be interpreted that claim 2 is only directed to said formula rather than to the method of claim 1. Clarification as to whether claim 2 is only a formula claim or a method claim.

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Claim 5 also contains this same unclarity issue. Clarification via clearer claim wording is requested.

Claim 15, line 1, cites the phrase "the morphometric descriptors" for which there is no antecedent basis either in claim 15 or in claim 13 from which claim 15 depends. Clarification is requested via clearer claim wording.

Claim 1, part (c), sets forth a formula with numerous undefined parameters therein. It is unclear whether generic parameters are meant or for someone attempting to understand the claim to search through the specification to reveal what values are meant thereby. This is also an issue in claims 2, 4, 5, and 12; as well as claims dependent from claim 1 directly or indirectly due to their dependence. Clarification via clearer claim wording is requested.

### **PRIOR ART**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 13-15, 19, and 21-23 are rejected under 35 U.S.C. 102(b) and (e)(2) as being clearly anticipated by Cabib et al. (P/N 5,784,162).

Cabib et al. discloses the practice of imaging for biological research and medical diagnostics in the abstract wherein the last line therein indicates the interpretation of data using a mathematical algorithm. In column 5, line 61, through column 6, line 63, the reference describes such imaging as being performed as directed to nucleic acids, via hybridization, FISH (as in instant claim 13) and to distinguish cancer from healthy cells (see especially column 6, lines 28-34). Such distinguishing is reasonably the usage of predictive parameters as in instant claim 14. A specific example as disclosed in the reference is set forth in Example 8 in columns 58-61 wherein cancerous pathologies are analyzed from samples from patients and subjected to various analyses such as principal component analysis, a type of statistical comparison analysis as required in instant claims 14 and correlation and DNA/RNA embodiments of instant claim 15.

No claim is allowed.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the Central PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)). The Central PTO Fax Center number is (703) 872-9306.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (571)272-0718. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (571)272-0722.

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Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instrument Examiner, Tina Plunkett, whose telephone number is (571)272-0549 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

February 20, 2004

  
ARDIN H. MARSCHEL  
PRIMARY EXAMINER